REMARKS

Claims 1-37, 87-90, and 161-171 are pending in the patent application. Independent claims 1, 22 and 161 have been amended to recite "wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package." Support for these amendments may be found at, for example, page 12, lines 2-12 and the examples of the present application. No new matter has been entered.

The Applicants are also submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca ("the DelDuca Third Declaration") (Exhibit 1) to assist in further explaining the applied prior art. The Applicants note that Mr. DelDuca previously submitted two declarations to assist in explaining the invention and showing the non-obviousness of the invention.[1]

Reconsideration of the pending claims is respectfully requested.

I Present Invention/Amended Claims

One important aspect of the present invention is that the present invention does not "fix" the color of the meat pigment to red with its use of carbon monoxide (CO), but rather the meat pigment tends to turn brown in a natural time period after removal of the second package that is substantially impermeable to oxygen. *See* page 12, lines 10-12 of the application; DelDuca Third Decl. ¶ 3. It is important to prevent the meat color from being "fixed" because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. *See* DelDuca Third Decl. ¶ 3. The term "fix" in this context does not mean that the color of meat pigment never changes to a brown color, but rather that the meat pigment does not turn brown in a natural time period after the meat pigment is exposed to the atmosphere. DelDuca Third Decl. ¶ 3.

Amended independent claims 1, 22 and 161 now specifically recite "wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package."

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[1] DelDuca Declaration filed on September 8, 2003 and DelDuca Second Declaration filed on June 16, 2004.

II. 35 U.S.C. § 103(a) Rejections

As acknowledged by the Examiner, U.S. Patent No. 6,054,153 to Carr ("Carr") and U.S. Patent No. 5,711,978 to Breen ("Breen") do not disclose, teach or suggest the use of carbon monoxide (CO). *See* pages 3 and 7 of the Office Action. The Office Action applies a number of references -- U.S. Patent No. 3,459,117 to Koch ("Koch"); U.S. Patent No. 4,522,835 to Woodruff ("Woodruff"); DE 1935566 A to Verbruggen ("Verbruggen"); and U.S. Patent No. 6,054,153 to Shaklai ("Shaklai") in an attempt to cure this deficiency in Carr and Breen. It would not have been obvious to combine Carr or Breen in view of other references such as Koch, Woodruff, Verbruggen and/or Shaklai to arrive at the present invention.

III. Applicants Previously Presented Evidence Of Non-Obviousness Of Independent Claims 1, 22 And 161

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants previously submitted evidence of non-obviousness in the form of two declarations in the Amendment and Response to Office Action that was filed on June 16, 2004 — the Hunt Declaration (Exhibit 1 of the Prior Response) and the DelDuca Second Declaration (Exhibit 2 of the Prior Response). Some of the evidence presented was directed to the understanding that those of ordinary skill in the art, prior to the Applicants' invention, believed that CO "fixed" the color of the meat pigment.

A. Prior To The Applicants' Invention, Those Of Ordinary Skill In The Art Believed That CO Fixed The Color Of The Meat Pigment

Specifically, the Applicants submitted evidence that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment:

(a) CO not allowed with fresh meat in the U.S. since at least 1962, until Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concern of "fixing" the meat color;

(b) In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question

"concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.";

(c) A previously applied reference in this application "The Storage Life Of Beef And Pork Packaged In An Atmosphere With Low Carbon Monoxide And High Carbon Dioxide" from *Meat Science* to Sorheim et al. ("Sorheim")) disclosed that its meat packaging systems with a modified atmosphere of "0.4% CO/60% CO_2/40% N_2 had a bright stable red colour that lasted beyond the time of spoilage." Abstract of Sorheim; and

(d) Dr. Hunt, who has extensive experience in the processing of meats using modified atmosphere packaging, stated that it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red.

B. The Applied References Of Shaklai And Koch Do Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

In response to the overwhelming submitted evidence that those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment, the Office Action states that (a) "Shaklai is relied on as further evidence that upon exposure to air, or removal of the first package as taught be Carr et al., CO is removable" and (b) "Koch et al. are relied on as evidence that CO is removably associated with a meat surface since the color is "fixed" for only a finite time after the CO-containing wrapper is removed." Pages 4 and 5 of the Office Action (similar passages are also cited at pages 7-9 of the Office Action).

Neither Shaklai nor Koch teaches or suggests the claimed limitation in independent claims "wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package," now specifically recited in independent claims 1, 22 and 161. Furthermore, there is no motivation to combine Shaklai and/or Koch with the other applied references in the pending rejections.

1. Shaklai Teaches That CO "Fixes" The Color Of The Meat Pigment (I.e., Extends Color Life)

Since Shaklai teaches that CO "fixes" the color of the meat pigment after exposure to the atmosphere, there would be no motivation to one of ordinary skill in the art to combine Shaklai

with (a) Carr, Koch and Woodruff; or (b) Breen, Koch, Woodruff and Verbruggen as in the pending rejections.

Specifically, Shaklai discloses exposing raw meat to an atmosphere consisting essentially of CO in which the meat is "completely immersed or saturated" with CO. *See* col. 5, lines 29-37. "More specifically, a cross-section of meat is completely immersed in or saturated to its core with carbon monoxide from the exposed surfaces through the entire cross-section (thickness) including its core region and retains the carbon monoxide until the meat is cooked. Thus, as stated above, the meat is preserved throughout its thickness." Col. 5, lines 38-43 of Shaklai.

Shaklai continues by stating that "[p]ractically all of the carbon monoxide (over 99.9%) taken up by meat will be maintained as hemoglobin and myoglobin (Hb/Mb) bound forms." Col. 5, lines 57-59. Shaklai also discloses that "[b]oth hemoglobin and myoglobin bind carbon monoxide much more strongly than oxygen." Col. 5, lines 66-67. "It is thought that the mechanism for carbon monoxide preserving of meat is the much greater affinity of myoglobin for carbon monoxide than for oxygen." Col. 6, lines 26-28 of Shaklai.

It is known to those of ordinary skill in the art that when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity 200 times greater than oxygen does with hemoglobin.[2] Therefore, one of ordinary skill in the art would expect that CO "fixes" the color of the meat pigment past its natural time period upon exposure to the atmosphere. DelDuca Third Decl. ¶ 4. In other words, because of the hemoglobin's high affinity towards CO, the pigment of the meat, prior to Applicants' invention, would not have been expected to degrade in a natural time period. DelDuca Third Decl. ¶ 4.

The examples of Shaklai also support that the meat pigment is "fixed" beyond its natural time period. Specifically, Example 4 of Shaklai (mentioned at page 5 of the Office Action) discloses that (a) meat treated with CO on day 14 had only a surface (less than 1 mm deep) being brown, while (b) meat treated with air was dark brown throughout. Col. 9, lines 40-50. Thus, it is clear that the meat pigment in Example 4 was "fixed" because it extended the color of meat pigment past its natural time period after being exposed to the atmosphere. This is further illustrated in Example 3 of Shaklai where the air-treated meat and CO-treated meat had different

[2] *See, e.g.,* Color Atlas & Textbook of Hematology, Wm Platt, 2nd edition 1979 (Exhibit 2) and DelDuca Third Decl. ¶4.

colors – the air-treated meat after 3 days was all brown and the CO-treated meat was a wine-red color. Col. 9, lines 10-19.

Thus, because Shaklai discloses "fixing" the color of the meat pigment, there would be no motivation to one of ordinary skill in the art to combine Shaklai with (a) Carr, Koch and Woodruff or (b) Breen, Koch, Woodruff; and Verbruggen as in the pending rejections because Shaklai discloses "fixing" the color of the meat pigment.

2. Koch Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of its CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with (a) Carr, Shaklai and Woodruff; or (b) Breen, Shaklai, Woodruff and Verbruggen as in the pending rejections.

Specifically, Koch discloses wrapping meat with a CO-containing film such that CO is transferred from the film to contact the surface of the meat. *See*, abstract. An object of Koch is to include a relatively small quantity of CO that is gradually released from the CO-containing film. Col. 2, lines 18-22. Koch discloses (a) covering primal cuts made at a slaughterhouse with a CO-containing film, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc. Col. 3, lines 4-8.

Since Koch discloses a large quantity of meat (primal cuts) exposed to a small quantity of CO, it would not be reasonable that the non-surface meat pigments of the primal cuts would have been exposed to CO. *See* DelDuca Third Decl. ¶ 7.

First, Koch does not disclose the exact weight of the primal cuts of meat. "Primal" cuts of meat at the time of the Koch disclosure (late 1960's), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. DelDuca Third Decl. ¶ 6. The term "subprimal" cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. DelDuca Third Decl. ¶ 6. Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat. DelDuca Third Decl. ¶ 6.

Second, the disclosure of Shaklai with 100% CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to

100% CO to turn the meat pigment to carboxymyoglobin. *See* col. 9, lines 11-28 of Shaklai and DelDuca Third Decl. ¶ 7. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-surface meat pigments to carboxymyoglobin. DelDuca Third Decl. ¶ 7.

Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film. DelDuca Third Decl. ¶ 7. It would be expected that the individually cut steaks and roasts sections of Koch that were not exposed to CO would degrade in a manner similar to other similar cuts of steaks and roasts that had also not been exposed to CO. DelDuca Third Decl. ¶ 8. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts not exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. DelDuca Third Decl. ¶ 8. Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film. DelDuca Third Decl. ¶ 8.

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with (a) Carr, Shaklai and Woodruff; or (b) Breen, Shaklai, Woodruff and Verbruggen as in the pending rejections.

In summary, neither Shaklai nor Koch teaches or suggests that the meat pigment upon exposure to CO does not "fix" the color of the meat pigment after exposure to the atmosphere.

IV. Independent Claims 1, 22 and 161

Therefore, the submitted evidence summarized above indicates that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment after exposure to the atmosphere. The applied references of Koch and Shaklai do not alter that conclusion. It would, therefore, be expected prior to the Applicants' invention that the CO levels disclosed in U.S. Patent No. 4,522,835 to Woodruff ("Woodruff") would "fix" the color of the meat pigment after exposure to the atmosphere. Thus, there would be no motivation to combine (a) Carr, Koch, Woodruff, Shaklai or any combination thereof; or (b) Breen, Koch, Woodruff, Verbruggen, Shaklai or any combination thereof.

Additionally, the Applicants presented compelling evidence directed to long-felt need and commercial success in the Amendment and Response to Office Action filed on June 16, 2004 that further supports the non-obviousness of the present invention.

Therefore, independent claims 1, 22 and 161 are not obvious in view of Carr, Woodruff, Breen, Verbruggen, Shaklai or any combination thereof and, thus, should be in a condition for allowance.

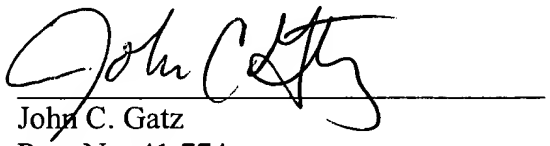
V. Dependent Claims 2-21, 23-37, 87-90 and 162-171

Dependent claims 2-21, 23-37, 87-90 and 162-171, which depend directly or indirectly on independent claim 1, 22 or 161, are not obvious in view of Carr, Woodruff, Breen, Verbruggen, Shaklai or any combination thereof for at least the same reasons discussed with respect to claims 1, 22 and 161. Thus, claims 2-21, 23-37, 87-90 and 162-171 should be in a condition for allowance.

VI. Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. Applicants are concurrently filing herewith a Request for Continued Examination (RCE) of this matter. Applicants are also filing a Petition for Two Month Extension of Time. The Applicants have enclosed a check in the amount of $1,240.00 for both the extension of time and Request for Continued Examination fees. It is believed that no further fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkens & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01080USPT.

Respectfully submitted,



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/915,150
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	July 25, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01080

THIRD DECLARATION OF GARY R. DELDUCA
UNDER 37 C.F.R. § 1.132

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

5/10/05
Date

Adrienne White

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

Dear Commissioner:

I, Gary R. DelDuca, declare that:

1. I hold a degree of B.S. in Mechanical Engineering From Rochester Institute of Technology in Rochester, New York that was obtained in 1980.

2. From 1980-1995, I worked as a developmental and senior engineer for Mobil Chemical Company, Plastics Division. As a developmental engineer, I worked in process and product development in the area of foam products. As a senior engineer, some of my responsibilities included designing specialized machinery that included machinery directed to stacking trays for meat processes. Mobil Chemical Company, Plastics Division was purchased by Tenneco Inc. in 1995. From 1995 to the present, I have been a Technical Manager for Tenneco Packaging Inc. in the area of modified atmosphere packaging (MAP) for meats. My responsibilities have included designing, developing, and implementing such modified atmosphere

packaging for meat and processes using the same. In 1999, Tenneco Packaging Inc. was renamed Pactiv Corporation ("Pactiv").

3. One important aspect of the present invention is that the present invention does not "fix" the color of the meat pigment to red with its use of carbon monoxide (CO), but rather the meat pigment tends to turn brown in a natural time period after removal of the second package that is substantially impermeable to oxygen. It is important to prevent the meat color from being "fixed" because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. The term "fix" in this context does not mean that the color of meat pigment never changes to a brown color, but rather that the meat pigment does not turn brown in a natural time period after the meat pigment is exposed to the atmosphere.

4. It is known to those skilled in the art that when hemoglobin in the red blood cells is exposed to CO, it has a much greater affinity than oxygen does with hemoglobin. In fact, when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity 200 times greater than oxygen with hemoglobin. Therefore, one skilled in the art would expect that CO "fixes" the color of the meat pigment past its natural time period upon exposure to the atmosphere. In other words, because of the hemoglobin's high affinity towards CO, the pigment of the meat, prior to Applicants' invention, would not have been expected to degrade in a natural time period.

5. U.S. Patent No. 3,459,117 to Koch discloses (a) covering primal cuts made at a slaughterhouse with a film that contains a small quantity of CO, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc.

6. "Primal" cuts of meat at the time of the Koch disclosure (late 1960's), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. The term "subprimal" cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat.

7. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-surface meat pigments, which were not exposed to CO, to carboxymyoglobin. This is supported by the disclosure of U.S. Patent No. 6,042,859 to Shaklai. The disclosure of Shaklai with 100%

CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to 100% CO to turn the meat pigment to carboxymyoglobin. Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film.

8. It would be expected that the individually cut steaks and roasts sections of Koch that were not exposed to CO would degrade in a manner similar to other similar cuts of steaks and roasts that had also not been exposed to CO. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts not exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film.

9. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 9, 2005

Gary R. DelDuca

Color Atlas & Textbook of Hematology
Wm Platt 2nd Ed 1979

bolic pool, to be used again in protein synthesis or serve as a source of energy. Verdohemoglobin is reduced at the γ methene bridge to yield free bilirubin (orange-red, insoluble, and nonfilterable by the kidneys), which passes out of the reticuloendothelial cells into the plasma, where it is loosely bound to albumin. This bilirubin-albumin complex is carried to the liver, where it is conjugated with glucuronic acid within the liver cells. Normally most of this soluble bilirubin-diglucuronide passes into the biliary canaliculi. A small amount of this soluble, conjugated bilirubin is regurgitated back into the plasma, where it is again loosely attached to albumin. Because it is insoluble, it cannot be filtered readily by the kidneys.

From the biliary canaliculi, most of the soluble bilirubin-diglucuronide passes into the common bile duct and thence into the intestinal tract, where the bacterial flora removes the glucuronic acid, leaving the free bilirubin to be reduced in accordance with the type of bacterial flora present. One of the reduction products is urobilinogen, a colorless complex consisting mostly of stercobilinogen. When broad-spectrum antibiotics are given to patients, the bacterial flora is markedly diminished. This decreases the amount of bilirubin reduced to urobilinogen, and therefore urobilinogen excretion is reduced. Bilirubin thereby becomes the main bile pigment found in the feces. After the patient is taken off these antibiotics, the bacterial flora gradually returns, first reducing bilirubin to d-urobilinogen and then to stercobilinogen predominantly. A small amount of intestinal tract urobilinogen complex is reabsorbed and excreted again through the liver, or it appears in the urine. When feces and urine are exposed to air, they are oxidized to the urobilin group of compounds.

HEMOGLOBIN COMPOUNDS

The main function of hemoglobin in body metabolism is as a respiratory pigment in the form of oxyhemoglobin (scarlet red). As erythrocytes flow along in single file in the delicate alveolar capillaries of the lung, the partial pressure (100 torr.) of oxygen in the alveolar air converts almost all the hemoglobin in these red blood cells to oxyhemoglobin, by a process of diffusion through the erythrocytic membrane. Because the association of oxygen and hemoglobin is loose and unstable, the oxygen readily diffuses back to the tissues for oxidative purposes, and the oxyhemoglobin then becomes reduced hemoglobin (dark red). There is, then, a concomitant release of base, which binds part of the incoming carbon dioxide. Carbon dioxide is also bound as a carbamate at the free amino groups of the hemoglobin molecule. A most important portion of the carbon dioxide diffuses from the plasma into the red blood cells, where catalysis by carbonic anhydrase joins it with water to form carbonic acid, which in turn dissociates into $(H)^+$ and $(HCO_3)^-$.

Carboxyhemoglobin is one of the abnormal hemoglobin pigments incapable of carrying oxygen. It is formed when hemoglobin in the red blood cells is exposed to carbon monoxide, which has an affinity 200 times greater for hemoglobin than oxygen does. When toxic amounts of carbon monoxide are present (from automobile exhaust fumes, for example), the blood is cherry red, and anoxia may result with subsequent death caused by irreversible tissue changes. Endogenous carbon monoxide production and subsequent respiratory excretion are related to heme degradation on a one-mole-to-one-mole basis. Since there is no other source of endogenous CO, measurement of its production rate accurately quantitates the catabolism of heme compounds, and thus also the rate of hemolysis.[25] Like oxyhemoglobin, carboxyhemoglobin is seen spectroscopically at 576 μ (Plate 8).

Methemoglobin is formed when hemoglobin in its deoxygenated state (reduced hemoglobin) is oxidized to the ferric form (iron normally exists in the ferrous state in the iron porphyrin complex of the heme portion of the hemoglobin molecule. See p.